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EXHIBIT 2

IôDP SA
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Contact: Marie-Laurence Borie, President
March 23, 2001

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Model Iô-3DUIMS " 3D Ultrasound Management System
   Classification Name: 90 IYO
   Common/Usual Name: 3D Ultrasound Image Management System

2. Equivalent legally marketed device: This product is similar in design and identical in function to the EchoTech 3D FreeScan, K980308

3. Indications for Use (intended use): Indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3- dimensional image processing.

4. Description of the device: It is an add-on accessory for existing ultrasound imaging systems, and is intended to record position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. It is intended as a general purpose digital 3D ultrasound image processing tool for radiology, neurology, gastroenterology, urology, surgery, orthopedics, oncology, obstetrics and gynecology. The device accepts various video formats, stores, and manipulates the images for display and printing.

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5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	EchoTech 3D FreeScan, K980308	"Model Iô-3DUIMS " 3D Ultrasound Management System
Indications for use	Indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3- dimensional image processing	SAME
Host platform	Standard PC platform with Windows NT	SAME, can also use Windows 95, 98, and 2000
Video capture	Matrox Meteor II	SAME
Position sensor	Electromagnetic	SAME

6. Testing information and Conclusion

In all material respects, the "Model Iô-3DUIMS " 3D Ultrasound Management System is substantially equivalent to EchoTech 3D FreeScan, K980308. Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2001

IôDP SA
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K011095
Model IO-3DUIMS (Virtual Probe)
3D Ultrasound Management System
Dated: April 6, 2001
Received: April 10, 2001
Regulatory Class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

j) Indications for Use

510(k) Number_____

"Model Iô-3DUIMS " 3D Ultrasound Management System is indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3- dimensional image processing. It is an add-on accessory for existing ultrasound imaging systems, and is intended to record position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. It is intended as a general purpose digital 3D ultrasound image processing tool for radiology, neurology, gastroenterology, urology, surgery, orthopedics, oncology, obstetrics and gynecology.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011095